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IN THE

Supreme Court of the United States

BAYER SCHERING PHARMA AG AND
BAYER HEALTHCARE PHARMACEUTICALS INC.,
Petitioners,

v.

BARR LABORATORIES, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Under 35 U.S.C. § 103(a) and this Court's precedents, a claimed invention is not patentable if it would have been "obvious" at the time it was made to a person having ordinary skill in the art. This Court has used terms like "plainly foreshadowed," "plainly indicated," "immediately recognized," and "predictable" to describe the standard.

Question presented: Whether the Federal Circuit has deviated from the statutory text and this Court's precedents by holding that an invention is "obvious" when there were a finite number of "viable" options that provided a so-called "reasonable expectation" of success, even though it remained necessary to conduct further experimentation, the results of which were unpredictable.

CORPORATE DISCLOSURE STATEMENT

Bayer Schering Pharma AG is wholly owned by Bayer AG, which is a publicly held corporation. Bayer HealthCare Pharmaceuticals Inc. is a wholly owned subsidiary of Schering Berlin Inc., which is a wholly owned subsidiary of Bayer HealthCare LLC, which is a wholly owned subsidiary of Bayer Corporation, which is a wholly owned subsidiary of Bayer AG.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively "Bayer") respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The order of the court of appeals denying Bayer's combined petition for panel rehearing and rehearing en banc (Pet. App. 129a) is unreported. The opinion of the court of appeals (Pet. App. 1a-19a) is reported at 575 F.3d 1341. The opinion of the district court (Pet. App. 20a-128a) is unreported.

JURISDICTION

The court of appeals entered judgment on August 7, 2009. Pet. App. 1a. The court of appeals denied Bayer's combined petition for panel rehearing and rehearing en banc on October 26, 2009. Pet. App. 129a. Bayer applied for an extension of time within which to file a petition for certiorari, and on December 18, 2009, the Chief Justice extended the time to February 23, 2010. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Section 103(a) of Title 35 of the United States Code provides:

> Conditions for patentability; non-obvious subject matter.
>
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the

> differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

STATEMENT

This case presents a fundamental question regarding the proper standard for deciding whether a claimed invention is patentable. Under section 103(a) of the Patent Act, a patent cannot issue if the claimed invention would have been "obvious" at the time it was made to a person having ordinary skill in the art. 35 U.S.C. § 103(a). In choosing the word "obvious," Congress codified more than 100 years of this Court's precedents. See *Graham* v. *John Deere Co.*, 383 U.S. 1, 14-15 (1966) (citing S. Rep. No. 82-1979, at 7 (1952)).

Throughout its decisions, this Court has used terms like "plainly foreshadowed," "plainly indicated," and "perfectly plain" to describe the proper standard. See *infra* at 12-17. Most recently, in *KSR*, the Court explained that a claimed invention is "obvious" if it resulted from trying a "predictable solution[]" that led to an "anticipated success." *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 421 (2007). All of these formulations are consistent with the ordinary meaning of the word "obvious," which is "plain" or "[e]asily discovered." See *Webster's New Collegiate Dictionary* 581 (2d ed. 1951) (defining "obvious" as "[e]asily discovered, seen, or understood; plain; evident").

The Federal Circuit, however, has designed and adopted its own test, which bears little resemblance

to *KSR*, the case law that preceded it, or any accepted meaning of "obvious." Specifically, the Federal Circuit has maintained that an invention was obvious to try, and therefore obvious, as long as there were a finite number of particular approaches that would have appeared as "viable option[s]" providing a so-called "reasonable expectation" of success. Pet. App. 12a-14a. The Federal Circuit has invalidated patents even when the discovery was "generally unpredictable" and additional experimentation was necessary. *Pfizer, Inc.* v. *Apotex, Inc.*, 480 F.3d 1348, 1364, 1366-67 (Fed. Cir. 2007).

The 2-1 decision below is only the latest Federal Circuit decision endorsing a lower "obviousness" standard than the one required by Congress and this Court. No other circuit has followed suit. And, indeed, some panels in the Federal Circuit have declined to do so as well, creating an internal inconsistency that is worthy of this Court's review.

The implications of the question presented are widespread and severe. The proper interpretation of Section 103(a) affects every patent application and all existing patents, which are subject to challenge in courts and to reexamination by the Patent and Trademark Office ("PTO"). The consequences of the Federal Circuit's decision are all the more significant now that the PTO has adopted the Federal Circuit's erroneous standard in its official guidelines for patent examiners. As the PTO Director recently acknowledged, "[s]ome have suggested that the Office is determining obviousness in a way that stifles innovation by refusing patents for truly inventive subject matter." David Kappos, Director, U.S. Patent & Trademark Office, The Impact of *KSR* (Nov. 24, 2009), www.uspto.gov/blog/.

To ensure the proper incentives for innovation, and to correct the Federal Circuit's plainly erroneous decision, this Court should grant certiorari.

Factual Background

At issue is Bayer's patent covering the oral contraceptive Yasmin®. The key active ingredient in Yasmin® is drospirenone, a compound that inhibits ovulation and that also can have the desirable effects of preventing acne and reducing bloating from water-retention. Pet. App. 2a. These attributes have contributed to Yasmin's® worldwide success.

In 1983, when Bayer decided to try to develop drospirenone as a birth-control pill, the project's success was far from guaranteed. Significantly, for a drug to be marketed as an oral contraceptive, it must be 99 percent effective on all women with a single dose. Pet. App. 4a; *id.* at 86a ("an oral contraceptive must be 99% effective"); *id.* at 97a (same). As the panel majority acknowledged, "'one dose must fit all.'" *Id.* at 4a. Throughout the drug's development, there were compelling reasons to doubt that drospirenone could meet that high standard.

For instance, drospirenone has poor water solubility. Pet. App. 2a-3a. That means the drug does not dissolve easily in liquid and, as a result, is not easily absorbed in the human body. Without proper absorption, a drug cannot serve as an oral contraceptive. *Id.*

There is a known technique for addressing this problem—namely, "micronization," or making the drug particles smaller. Micronization increases a drug's dissolution rate and thereby improves absorption. Pet. App. 2a-3a, 26a. However, micronzation would also exacerbate another problem: Drospirenone degrades in acid. Pet. App. 2a, 12a,

70a. Indeed, existing literature taught that in acidic environments comparable to the stomach, drospirenone loses its desired properties. *Id.* at 2a, 70a. And the leading drug formulation textbook, by Robert Aulton, observed that "micronization may increase the extent of drug degradation." *Id.* at 70a. Needless to say, excessive degradation would prevent drospirenone from being 99 percent effective in all women, rendering it unfit as a contraceptive. *Id.* at 2a.

Despite these uncertainties and conflicting scientific considerations, Bayer began testing micronized drospirenone and considered two possible forms of the drug—an uncoated tablet and a coated tablet. Drug developers typically designed uncoated tablets that would immediately release in the stomach. But, because of drospirenone's acid-sensitivity, administering it in an uncoated tablet could result in degradation in the stomach's acid that would render the drug ineffective as an oral contraceptive. Pet. App. 15a, 34a-35a.

To deal with this concern, literature such as the Aulton textbook suggested covering the drug tablet with an "enteric coating." Pet. App. 74a. The enteric coating would protect the drug from stomach acid and release it only in the less acidic small intestine. *Id.* at 3a, 74a. However, use of a coating created another source of scientific uncertainty. The coating could reduce the drug's availability and lead to varying response times from dose-to-dose and from patient-to-patient. *Id.* at 3a-4a. That potential unavailability and variability raised issues as to whether a coated drospirenone tablet would solve the problem at hand, because a birth control pill must provide a consistent, effective dose on all women. *Id.* at 75a.

Nonetheless, because a coated tablet seemed more likely to succeed than an uncoated tablet, Bayer

initially focused its clinical studies on the coated tablet. Pet. App. 4a-5a, 36a-37a. Bayer spent five years testing the coated tablet, and then, to assess just how much protection it provided against stomach acid, Bayer conducted a clinical trial comparing the coated tablet against the uncoated one. *Id.* at 4a-5a, 38a-39a. Bayer expected to find that the uncoated tablet would make less drospirenone available to the body than the coated tablet. *Id.* at 5a. To Bayer's "surprise," however, the uncoated tablet resulted in the same amount of drospirenone making it into the bloodstream. *Id.* at 5a-6a, 39a.

The uncoated tablet's unexpected effectiveness led Bayer to change course and begin developing drospirenone without the enteric coating. Pet. App. 6a, 39a. Between 1989 and 1997, Bayer performed at least five clinical trials in Europe testing the effectiveness of drospirenone and accompanying compounds at different dosages. *Id.* at 39a-42a. To confirm the effectiveness of the uncoated tablet in more diverse populations, Bayer also conducted a clinical trial in the United States. *Id.* at 42a-43a. The U.S. study yielded positive results in 1998—*15 years* after Bayer began its work. Bayer then sought approval from the U.S. Food and Drug Administration ("FDA") to market the drug. *Id.* at 42a-44a. In 1999, FDA approved Yasmin® for sale in the United States. *Id.* at 44a.

That same year, Bayer filed a patent application for its formulation of micronized drospirenone in an uncoated tablet. Pet. App. 44a. In September 2004, U.S. Patent Number 6,787,531 ("'531 Patent") issued. *Id.* at 6a. The patent examiner found that the patent claims were valid and nonobvious given the scientific uncertainty in the field and the existing literature's teachings that micronized, uncoated drospirenone

would likely degrade too rapidly in stomach acid to function as a contraceptive. *Id.*

Lower Court Proceedings

1. In 2005, Respondent Barr Laboratories ("Barr") sought FDA approval to market a generic version of Yasmin®. Bayer filed an infringement action against Barr, and Barr asserted that the patent was invalid.

After a bench trial, the district court held that the '531 Patent was invalid as obvious under 35 U.S.C. § 103(a). The court acknowledged that Bayer spent five years trying to develop a coated drospirenone tablet before being "surprised" by the effectiveness of an uncoated tablet. Pet. App. 38a-39a. Moreover, the court found that, even after Bayer conducted multiple clinical tests in Europe, additional testing through 1998 in the United States was "necessary to determine the effectiveness" of the uncoated tablet in the more diverse U.S. population. *Id.* at 112a.

But, despite this necessary and exhaustive experimentation in the face of scientific uncertainty, the district court opined that a drug formulator of ordinary skill would have viewed micronization as a "viable option." Pet. App. 72a. The court found that the formulator "would not [have] rule[d] out" developing uncoated, micronized drospirenone, *id.* at 76a, even though its effectiveness "require[d] verification through precise" laboratory and clinical testing. *Id.* at 89a. Based on those findings, the court concluded that formulating uncoated, micronized drospirenone was obvious. *Id.* at 99a.

2. A divided panel of the Federal Circuit affirmed, agreeing with the district court that uncoated, micronized drospirenone was a "viable known option to consider." Pet. App. 14a. The majority began its analysis by quoting *KSR*, *id.* at 9a ("'a finite number

of identified, predictable solutions'"), but then purported to recast the decision in terms of pre-*KSR* Federal Circuit precedent. *Id.* at 9a-10a. Under such precedent, an invention is not invalid for having been obvious to try if (a) "the inventor would have had to try all possibilities in a field unreduced by direction of the prior art," or (b) the prior art was "vague" and "'gave only general guidance as to the particular form of the claimed invention or how to achieve it.'" *Id.* at 10a (quoting *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)). The majority held that "the *KSR* requirement that the identified solutions be 'predictable'" "expresses the same idea as" Federal Circuit precedent that focuses on whether the prior art was "vague" or "general." *Id.*

The panel majority then turned to the finding that micronizing an acid-sensitive drug like drospirenone would have been "a viable option." Pet. App. 12a. The majority recognized that drospirenone's acid sensitivity would have counseled toward using a coated tablet, and did not dispute the district court's finding that "Aulton recognizes the *necessity* of an enteric coating to the formulation of acid-sensitive drugs." *Id.* at 13a (emphasis added). But the majority observed that the coated tablet would have "introduce[d] drawbacks" of its own, namely the unavailability and variability problems caused by coating. *Id.* The majority also noted that a drug related to drospirenone was known to absorb in the human stomach before degrading. *Id.* at 13a-14a. Thus, the panel reasoned, a drug formulator "had a viable known option to consider with micronized, unprotected drospirenone, and a reasonable expectation that drospirenone would perform similarly (even if not identically)" to the related drug. *Id.* at 14a

(citing *O'Farrell*, 853 F.2d at 903-04, for "reasonable expectation of success" test).

Because both the coated and the uncoated tablets remained viable possibilities, the panel determined that the drug formulator would have "reached a crossroads where he must choose between two known options." The majority labeled these "a finite number of identified, predictable solutions," relying on the court's recasting of the *KSR* predictability test. Pet. App. 15a. The majority reasoned, first, that the inventor "would not have been required to try all possibilities in a field unreduced by prior art." *Id.* Additionally, the court explained, "the prior art was not vague in pointing toward a general approach or area of exploration, but rather guided the formulator precisely to the use of either a normal [uncoated] pill or an enteric-coated pill." *Id.* The court thus concluded that formulating uncoated, micronized drospirenone was obvious. *Id.*

3. Judge Newman dissented. She noted that "the standard confronting Bayer scientists was high" because "contraceptives require complete effectiveness." Pet. App. 17a. Only by engaging in "hindsight science," Judge Newman explained, could the majority find "that it would have been obvious to expose [drospirenone] to acid, although it was not obvious to the scientists working on the project." *Id.* at 17a-18a. In essence, the majority "rule[d] that scientists should have 'tried' that which they believed would fail." *Id.* at 17a.

Judge Newman objected especially to the majority's legal test. Pet. App. 18a. She explained that "'viability' is not the standard." *Id.* "'Viability' implies that the experiment may or may not succeed." *Id.* The majority had thus "departed from the statutory standard." *Id.*

Bayer filed a petition for panel rehearing and rehearing en banc, which the Federal Circuit denied. Pet. App. 129a.

REASONS FOR GRANTING THE PETITION

Disregarding 150 years of this Court's precedents, the panel majority applied a counter-textual "obviousness" standard. According to the panel majority, a claimed invention is "obvious," and therefore not patentable, as long as it resulted from trying one of a finite number of particular approaches that would have appeared as mere "viable options" providing a so-called "reasonable expectation" of success—even though it remained necessary to conduct further experimentation, the results of which were wholly unpredictable.

This erroneous standard stems from a decades-old line of Federal Circuit cases that conflicts with the test applied by this Court. Consistent with the ordinary meaning of the word "obvious," this Court has used terms like "plainly foreshadowed," "plainly indicated," "immediately recognized," and "predictable" to describe the statutory standard. *See infra* at 12-17. These terms all reflect the high threshold for obviousness and the fact that, if actual experimentation was necessary and the results were unpredictable, the invention was not obvious. The Federal Circuit, by contrast, has redefined the test to speak of "viable options" and has invalidated patent claims even when the invention was "not predictable." *See infra* at 17-22.

The Federal Circuit's test also conflicts with the decisions of *every* other circuit to have addressed the issue. Indeed, even some Federal Circuit judges have expressed disagreement with the test, leading to divided and inconsistent opinions. The PTO, how-

ever, has enshrined the Federal Circuit's standard in its official guidance to patent examiners. As a result, day-in and day-out, the PTO is applying an improper "obviousness" test to patent applications and challenges to existing patents. The effect is to deny valuable patent rights to inventors whom Congress intended to protect.

To make matters worse, the Federal Circuit now places more emphasis on its erroneous standard than it did before *KSR*. Prior to *KSR*, the Federal Circuit applied its improper standard only as the second prong of a two-part test. The first prong asked whether existing literature provided an explicit teaching, suggestion, or motivation to make the claimed invention. 550 U.S. at 419. In *KSR*, the Court rejected that inquiry as overly rigid and exacting. *Id.* at 421. The Court also reiterated that obviousness depends on whether a particular combination would lead to predictable results. *Id.* Since then, however, the Federal Circuit has continued to apply its previous approach, but shorn of the first prong. The errant second prong thus bears more weight than it did previously.

Absent this Court's correction, patents and patent applications covering genuine innovations—the discoveries of which were not predictable—are vulnerable merely because the inventor relied on particular, identified methods of research and development using existing building blocks. The decision below undermines the incentives for Innovation in highly unpredictable fields that employ enormously expensive and lengthy, but systematic and logical experimentation, because patent examiners and courts may deem the eventually successful path to have been a "viable option."

What makes the Federal Circuit's ruling so harmful is that innovation is critical to numerous endeavors vital to our economy. The incentives to prompt investment are nowhere more important than in the pharmaceutical arts because innovations in that field directly improve people's health. The consequences of the decision below plainly warrant this Court's review.

I. THE FEDERAL CIRCUIT'S STANDARD IS INCONSISTENT WITH SECTION 103 AND THIS COURT'S PRECEDENTS.

A. Section 103 And This Court's Decisions Require A Showing That The Claimed Invention Was "Obvious."

The language of the statute is straightforward and unambiguous. Under 35 U.S.C. § 103(a), an invention is not patentable if "the subject matter as a whole would have been *obvious* at the time the invention was made to a person having ordinary skill in the art" (emphasis added). The only basis for denying a patent under this provision is "obvious[ness]."

1. As this Court recognized, when Congress enacted section 103(a) in 1952, it intended to codify the Court's long-established test for discerning a true "invention" worthy of patent protection. *Graham*, 383 U.S. at 14-15 (citing S. Rep. No. 82-1979, at 7 (1952)); see, *e.g.*, *R.R. Supply Co.* v. *Elyria Iron & Steel Co.*, 244 U.S. 285, 290 (1917) (invalidating patent based on "the obviousness of the elements necessary to the solution of this problem"); *Hotchkiss* v. *Greenwood*, 52 U.S. (11 How.) 248, 267 (1850) (first establishing the test). From various judicial formulations, Congress chose the term "obvious," meaning "[e]asily discovered, seen, or understood; plain;

evident." *Webster's New Collegiate Dictionary* 581 (2d ed. 1951). Congress thus approved the decisions of this Court, which invalidated a patent only when the claimed solution to a problem would have been "plain" to a person skilled in the art. *Id.*

Consistent with the ordinary meaning of the term, this Court's pre-1952 decisions invalidated patents when the claimed invention was "plainly foreshadowed" or "plainly indicated" in the prior art. *E.g.*, *Textile Mach. Works* v. *Louis Hirsch Textile Machs., Inc.*, 302 U.S. 490, 498 (1938); *Altoona Publix Theatres, Inc.* v. *Am. Tri-ergon Corp.*, 294 U.S. 477, 486 (1935). The Court struck down patents when the claimed solution to a problem would have been "perfectly plain," *Dow Chem. Co.* v. *Halliburton Oil Well Cementing Co.*, 324 U.S. 320, 327 (1945), or would have been "immediately recognized" by one skilled in the art, *DeForest Radio Co.* v. *Gen. Elec. Co.*, 283 U.S. 664, 682 (1931); *see also Graham*, 383 U.S. at 25 (invalidating patent where person of ordinary skill "would *immediately see* that the thing to do was what Graham did") (emphasis added); *Phillips* v. *Detroit*, 111 U.S. 604, 608 (1884) (invalidating patent where claimed solution would have "naturally and spontaneously occur[ed] to any skilled mechanic").

These formulations all connote a high standard of obviousness, and the Court applied them as such. Only when the patent's successful resolution of the problem at hand was "perfectly plain" or predictable, rather than "unexpected," would the Court invalidate the patent. *E.g.*, *Dow Chem.*, 324 U.S. at 327.

This was true even if the patent was composed only of elements that were already "known in the prior art." *KSR*, 550 U.S. at 418-19. As the Court observed, "inventions in most, if not all, instances

rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* Thus, combinations of known elements could still be patented when, for example, they yielded "unexpected" results, *United States* v. *Adams*, 383 U.S. 39, 51 (1966), or when "known disadvantages" would have "naturally discouraged" a person of ordinary skill from attempting a combination that happened to succeed, *id.* at 52. The test, at bottom, was whether the invention was "plainly foreshadowed." *E.g.*, *Textile Mach. Works*, 302 U.S. at 498.

Applying this high standard, the Court affirmed inventions as patentable when their discovery could not have been anticipated without additional experimentation. For example, in *Eibel Process Co.* v. *Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923), the Court approved a patent on an improvement to a standard paper-making machine. Existing machines drained water from pulp by moving it along an incline of only several inches. *Id.* at 54-55. The patent demonstrated that by increasing the incline, the pulp could travel at much higher speeds while still draining sufficiently. *Id.* Even though the patent used known components, each working according to known principles, the Court upheld the patent because "there [was] no means, short of actual experiment[ation], to enable one to anticipate [the] results." *Id.* at 62 (noting numerous, interrelated factors bearing on the problem at hand). The inability to predict the results beforehand meant that the patent "was invention rather than the mere obvious and simple application of known natural forces." *Id.*

Other decisions of this Court stand for the inverse proposition that a claimed invention is obvious if further experimentation was not needed to enable one to predict its success. For example, the Court invalidated a patent for quick-drying printing ink because the essential element—a solvent with a sufficiently low boiling point—was selected, not by experimentation, but simply by referencing published lists of solvents' boiling points. *Sinclair & Carroll Co.* v. *Interchemical Corp.*, 325 U.S. 327, 333-34 (1945). Likewise, the Court deemed obvious a patent that merely applied a familiar combination of chemicals with well-known attributes to the field of oil-well drilling. *Dow Chem.*, 324 U.S. at 327. The patent was obvious because the claimed innovation required "[n]o new mental or physical operation," as it was "perfectly plain" that the chemicals would perform as anticipated in the oil wells. *Id.*; *see also id.* at 331 (explaining that as soon as the need arose, the claimed solution "was suggested immediately and without effort").

2. In *KSR International Co.* v. *Teleflex Inc.*, 550 U.S. 398 (2007), the Court re-affirmed these long-established principles. After rejecting the Federal Circuit's rule that a patent combining known elements is obvious only if the prior art contained an explicit teaching, suggestion, or motivation to combine the elements, *id.* at 414, 419, the Court held that the obviousness inquiry focuses on predictability, see, e.g. *id.* at 421. In evaluating a patent, a court should ask whether a "combination of familiar elements according to known methods . . . yield[ed] *predictable* results." *Id.* at 416 (emphasis added); see also *id.* at 416 ("[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known

in the field, the combination must do more than yield a predictable result."); *id.* at 417 ("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability."); *id.* (explaining that, under Court precedent, the test is "whether the improvement [to be patented] is more than the *predictable* use of prior art elements according to their established functions").

The Court made clear that the predictability standard governs equally when a plaintiff contends that the invention was "obvious to try":

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, *predictable solutions*, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the *anticipated success*, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Id. at 421 (emphases added). *KSR* thus dictates that an invention is "obvious" for having been obvious to try only when there were "predictable solutions" that led to an "anticipated success." *Id.* This formulation is perfectly consistent with the Court's prior expressions of the statutory standard. *See id.* at 417.

KSR also affirmed the "corollary principle" that "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *Id.* at 416. Assessing predictability thus requires considering whether existing art "warned that risks were involved" in the approach

that turned out to succeed. *Id.* (discussing *Adams*, 383 U.S. at 51-52).

Under this standard, an invention is not obvious merely because there were a limited number of viable approaches to a problem. Rather, the person of ordinary skill must also have been able to predict a solution beforehand. As the Court previously explained, when an invention's success was not predictable, but resulted from "actual experiment-[ation]," *Eibel*, 261 U.S. at 62, the invention is patentable.

B. The Federal Circuit's Standard Cannot Be Squared With Section 103 Or This Court's Decisions.

Despite this clear guidance, the panel majority applied a fundamentally different test, under which an invention is obvious as long as it resulted from trying one of a finite number of particular approaches that would have appeared as mere "viable options" providing a so-called "reasonable expectation" of success. Drawn from a decades-old line of Federal Circuit precedent, this test conflicts with *KSR*, the 150 years of this Court's case law that preceded it, and the text of Congress's enactment. Because the Federal Circuit has badly misconstrued the statutory standard, this Court should grant certiorari.

1. The panel majority began its analysis on the right foot, quoting *KSR*'s "predictable solutions" standard. Pet. App. 9a. But the panel majority abruptly abandoned the test by defining "predictability" as something else entirely. According to the panel majority, under Federal Circuit precedent, the "*KSR* requirement that the identified solutions be 'predictable'" is satisfied if the solutions guided by the prior art are "particular," as opposed to "vague" or

"'general.'" *Id.* at 10a (quoting *In re O'Farrell*, 853 F.2d at 903); see also *id.* at 15a ("[T]he prior art was not vague in pointing toward a general approach or area of exploration, but rather guided the formulator precisely to the use of either a normal pill or an enteric-coated pill, thus avoiding the second pitfall of *O'Farrell*."). Thus, the panel transformed the "predictability" inquiry into a question about whether the potential solutions were "particular."

The majority then confirmed that it was departing from this Court's precedents. In stark contrast to this Court's decisions equating "obvious" with "predictable," "plainly foreshadowed," and "plainly indicated," *KSR*, 550 U.S. at 421; *Textile Mach. Works*, 302 U.S. at 486, *Altoona Publix Theatres*, 294 U.S. at 458-89, the panel majority focused on whether the invention was a "viable known option to consider." Pet. App. 14a; *id.* at 12a ("[The district court] concluded that a person having ordinary skill would have seen [micronization] as a viable option."); *id.* ("So there remains adequate support for the conclusion that micronization was a viable option."). Indeed, the most the panel could say was that micronized, uncoated drospirenone was a "viable" option with a "reasonable expectation" of "perform-[ing] similarly (even if not identically)" to a related compound. *Id.* at 14a (quoting *O'Farrell*, 853 F.2d at 903-04, for the proposition that obviousness is found when the invention had a "reasonable expectation of success").

Yet, "viable options" that give rise to "reasonable expectations" are not the same things as "predictable solutions" that generate "anticipated success[es]." As the dissent explained, "'[v]iability' implies that the experiment may or may not succeed." Pet. App. 18a. Such a solution certainly is not "obvious," "perfectly

plain," or "immediately recognize[able]"—the standard set by the statute and this Court. 35 U.S.C. § 103(a); *Dow Chem.*, 324 U.S. at 327; *DeForest Radio*, 283 U.S. at 682.

2. Further, the panel majority's standard runs roughshod over the Court's distinction between results that required "actual experiment[ation]," *Eibel*, 261 U.S. at 62, and results that were "suggested immediately and without effort." *Dow Chem.*, 324 U.S. at 331. Before Bayer could predict the success of uncoated drospirenone, it undoubtedly had to conduct "actual experimentation." As the district court found, determining whether uncoated drospirenone absorbed or degraded in the body "*require[d] verification through precise in vivo and in vitro [i.e., clinical and laboratory] testing.*" Pet. App. 89a (emphasis added). All the district court could conclude was that "[t]he person of ordinary skill in the art *would not rule out* formulating a micronized drospirenone without enteric coating in order to overcome variability concerns." *Id.* at 76a (emphasis added).

Indeed, Bayer scientists labored for five years on testing the coated tablet precisely because they could not predict that the uncoated tablet would be 99 percent effective. Pet. App. 35a-36a. And, even after Bayer switched course in 1988 to focus on the uncoated tablet, another ten years of testing was conducted. Bayer first administered multiple clinical tests in Europe. *Id.* at 39a-40a. After that, it was still "necessary," according to the district court, for Bayer to complete additional clinical trials in the United States in order "to determine effectiveness" of the uncoated tablet in the more diverse U.S. population. *Id.* at 112a; see also *id.* at 42a.

The panel majority did not dispute these findings. Instead, the panel simply noted that a person with ordinary skill in the art would have "reached a crossroads where he must choose between two known options." Pet. App. 15a. But reaching a "crossroads" of two possible options, neither one of which is a predictable success, and both of which might fail, is a far cry from establishing that the eventual solution is "plainly indicated" or "immediately recognized." *Cf. Altoona Publix Theatres*, 294 U.S. at 486; *DeForest Radio Co.*, 283 U.S. at 682. Moreover, the panel majority's approach is unduly simplistic. A third option would have been to abandon the efforts to develop drospirenone as an oral contraceptive. Of course, then millions of women would have been denied a safe and effective oral contraceptive—a result the patent laws are clearly designed to avoid.

3. The decision below is by no means the only Federal Circuit decision that has erroneously eschewed this Court's predictability test. In *Pfizer, Inc.* v. *Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007), for example, the Federal Circuit accepted the trial court's finding that "it was *generally unpredictable* as to whether a particular salt would form and what its exact properties would be." *Id.* at 1364 (emphasis added). Nevertheless, the Federal Circuit held that the invention was obvious, because "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Id.*

Likewise, the court in *In re Longi*, 759 F.2d 887, 897 (Fed. Cir. 1985), invalidated a patent despite finding that the claimed compound's desirable functionality was "not . . . predictable." And, in *Verlander* v. *Garner*, 348 F.3d 1359, 1377 (Fed. Cir. 2003), the Federal Circuit invoked the "viable option"

standard in striking down a patent on an invention that "was expensive, technically challenging, and laborious." See also, *e.g.*, *Pharmastem Therapeutics, Inc.* v. *Viacell, Inc.*, 491 F.3d 1342, 1364 (Fed. Cir. 2007) (stating that *O'Farrell*, which spoke only of "a reasonable expectation of success," 853 F.2d at 904, provides "useful guidance for determining whether the expectation of success from a particular line of inquiry is great enough to render a resulting invention obvious"), *cert. denied*, 128 S. Ct. 1655 (2008).[1]

4. To be sure, on occasion, certain panels of the Federal Circuit have applied the correct "predictable solution" standard. *E.g.*, *Sanofi-Synthelabo* v. *Apotex, Inc.*, 550 F.3d 1075, 1089-90 (Fed. Cir. 2008) (affirming finding of nonobviousness where evidence showed that "result" of the process leading to the claimed invention "was unpredictable"), *cert. denied* 130 S. Ct. 493 (2009). But, that inconsistency only bolsters the case for certiorari. Federal Circuit judges' conflicting opinions on the question presented have emerged in divided panel decisions, like the one below, and in dissents from denials of rehearing petitions. See, *e.g.*, *Pharmastem*, 491 F.3d at 1379-84; *Pfizer, Inc.* v. *Apotex, Inc.*, 488 F.3d 1377 (2007) (Newman, Lourie, & Rader, JJ., dissenting from denial of petition for rehearing en banc). As one

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[1] In the proceedings below, petitioners urged the Federal Circuit to apply the "reasonable expectation of success" test in a manner consistent with *KSR*'s predictability standard. *See, e.g.*, Bayer Opening Br. 33 (July 9, 2008) (equating "'predictable solutions'" with "'reasonable expectation of success'"); Bayer Combined Petition for Panel Rehearing and Rehearing En Banc 4-5 (Sept. 4, 2009) (same). The court, however, declined to do so, defining away "predictability" and settling on the "viable options" framework.

commentator observed, the Federal Circuit's recent decisions "defy a coherent synthesis of post-*KSR* chemical obviousness jurisprudence." Janice M. Mueller, *Chemicals, Combinations, and "Common Sense": How the Supreme Court's* KSR *Decision is Changing Federal Circuit Obviousness Determinations in Pharmaceutical and Biotechnology Cases*, 35 N. Ky. L. Rev. 281, 300-01 (2008). This case provides the Court with a perfect vehicle to clarify this vital issue of patent law.

The division of opinion among judges on the Federal Circuit frustrates Congress's purpose in creating the court to promote "'nationwide uniformity in patent law.'" *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989) (quoting H.R. Rep. No. 97-312, at 20 (1981)) (internal quotation marks omitted). The current divide among Federal Circuit judges sends mixed signals to patent examiners and subjects the rights of patent holders and challengers to the luck of the panel draw. This Court has previously granted certiorari to resolve disagreement within the Federal Circuit, and it should do so again here. *E.g.*, *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997).

II. THE DECISION BELOW CONFLICTS WITH DECISIONS OF EVERY CIRCUIT TO HAVE ADDRESSED THE ISSUE.

This Court's review is warranted also because the decision below conflicts with the decisions of every other circuit that has addressed the issue. Although the Federal Circuit decides almost all of the cases raising patent validity issues, it does not have exclusive patent jurisdiction. Under 28 U.S.C. §§ 1295(a)(1), 1338, regional circuits retain jurisdiction over cases in which patent issues do not arise

under a well-pleaded complaint, such as cases in which a defendant raises the patent issue in a counterclaim. *Holmes Group, Inc.* v. *Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 833-34 (2002).

The Court thus continues to monitor circuit splits in order to "identify[] questions that merit this Court's attention." *Id.* at 839 (Stevens, J. concurring). Decisions of regional circuits provide an important point of comparison, serving as an "antidote to the risk that the specialized court may develop an institutional bias." *Id.*

For those reasons, the fact that *no other circuit* employs the obviousness standard applied by the panel majority counsels strongly in favor of review. Most circuits simply apply the statutory term "obvious" without adding an inconsistent gloss.[2] No

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[2] *Colortronic Reinhard & Co.* v. *Plastic Controls, Inc.*, 668 F.2d 1 (1st Cir. 1981) (affirming invalidity where the patent was "but an obvious application of the prior art" and "surely the type of advance a person of ordinary skill in the art would discover"); *Digitronics Corp.* v. *N.Y. Racing Ass'n*, 553 F.2d 740, 745, 748 (2d Cir. 1977) (affirming invalidity finding where claimed innovation "was just what could have been predicted when those means were applied to perform that function" and "fully anticipated"); *Black & Decker Mfg. Co.* v. *Sears, Roebuck & Co.*, 679 F.2d 1101, 1103 (4th Cir. 1982) (per curiam) (affirming validity finding by applying solely the statutory test of "obvious"); *May* v. *Am. Sw. Waterbed Distribs., Inc.*, 715 F.2d 876, 881-83 (5th Cir. 1983) (affirming invalidity finding by applying solely the statutory test of "obvious"); *Armco, Inc.* v. *Republic Steel Corp.*, 707 F.2d 886, 890 (6th Cir. 1983) (affirming validity of patent where prior state of the art led to conclusion that "the patent design must not have been all that obvious"); *Square Linder 360°, Inc.* v. *Chisum*, 691 F.2d 362, 369 (8th Cir. 1982) (affirming validity by framing the "pertinent question" as "whether, considering the invention as a whole, it would have been obvious to combine the elements in the claimed relationship"); *Omark Indus., Inc.* v. *Textron, Inc.*, 688 F.2d

decision from any other circuit applies the lower standard of "viable options," or "reasonable expectation[s]," applied by the panel majority.

For example, in *Eli Lilly & Co.* v. *Premo Pharmaceutical Laboratories, Inc.*, 630 F.2d 120 (3d Cir. 1980), the Third Circuit held that a claimed chemical compound was patentable if it "exhibits uses or traits that, at the time of their discovery, were not *predictable*." *Id.* at 130 (emphasis added). The Third Circuit distinguished between predictability in research *methods* and predictability in *results*, explaining that although the "manner of producing [the compound] was readily predictable and performable," the compound was nonetheless patentable because its "real advancement over the prior art"—a high absorption rate—"was totally unexpected, even by the chemists who proposed its synthesis." *Id.* at 131.

Likewise, the Seventh Circuit in *Novo Industri A/S* v. *Travenol Laboratories, Inc.*, 677 F.2d 1202 (7th Cir. 1982), addressed the argument that an experiment leading to the discovery of a known enzyme's useful properties would have been obvious to try. *Id.* at 1208. The court affirmed the patent's validity because "the *results* of such a trial could [not] have been *anticipated*." *Id.* (emphases added) The court explained that "[t]he test of obviousness is whether the invention as a whole would be obvious, including the nature of the results obtained." *Id.* Because the

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1242, 1248 (9th Cir. 1982) (stating that the "key determination" is the statutory term "obvious"); *Lam, Inc.* v. *Johns-Manville Corp.*, 668 F.2d 462, 469-70 (10th Cir. 1982) (affirming validity of patent by applying statutory term "obvious"); *Scandiamant Aktiebolag* v. *Comm'r of Patents*, 509 F.2d 463, 472 (D.C. Cir. 1974) (reversing finding of invalidity by applying statutory term "obviousness" and noting "new and unexpected result[s]").

results were unexpected, the invention was not obvious. *Id.* And, in *Eli Lilly & Co.* v. *Generix Drug Sales, Inc.*, 460 F.2d 1096 (5th Cir. 1972), the Fifth Circuit similarly held that an invention was not obvious to try unless it would "logically or predictably" result in the helpful uses sought. *Id.* at 1103.

These decisions highlight the panel majority's errors. An innovation is not obvious simply because there were a discrete number of particular "viable options." The solution must have been predictable. Because the Federal Circuit is out of step with *every* other circuit to have addressed the issue, this Court's review is warranted.

III. THE QUESTION PRESENTED RECURS FREQUENTLY AND HAS PROFOUND IMPLICATIONS FOR INDUSTRIES DEPENDENT UPON RESEARCH AND DEVELOPMENT.

This Court should grant review because the question presented has broad application and profound consequences for scientific research and development. Left unchecked, the Federal Circuit's erroneous standard would cast a shadow over many existing patents and may deter firms from undertaking the resource-intensive research that drives innovation.

1. The fact that the question presented concerns basic "patentability standards" and the "application of prior Supreme Court precedent" to the patent system is reason enough for the Court to grant review. Eugene Gressman et al., *Supreme Court Practice* 287 (9th ed. 2007). Certiorari is all the more necessary because the PTO has enshrined the Federal Circuit's improper standard in its official

guidance to patent examiners. Responding to *KSR*, the PTO issued new guidelines for reviewing patent applications and reexamining existing patents. Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International v. Teleflex Inc.*, 72 Fed. Reg. 57526, 57529 (Oct. 10, 2007).

Rather than hewing to *KSR*, the PTO guidelines point examiners to several recent Federal Circuit decisions that apply the same incorrect standard applied by the panel majority. *Id.* at 57532-33. For example, the guidelines highlight *Pfizer, Inc.* v. *Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007), which held an innovation to be obvious even though a person of ordinary skill had no fewer than 53 compounds to try in solving a problem, and the compounds' behaviors were "generally unpredictable." *Id.* at 1364. Despite that blatant inconsistency with *KSR*'s emphasis on predictability, the PTO instructs examiners that having 53 unpredictable compounds to try is "an acceptable number to form 'a reasonable expectation of success.'" 72 Fed. Reg. at 57532. Now entrenched in the PTO's current operations, the Federal Circuit's standard "cast[s] doubt on many existing patents," as well as meritorious future patent applications. *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 727-28 (2002) (granting certiorari when Federal Circuit decision undermined validity of existing patents).

It therefore comes as no surprise that the PTO Director recently acknowledged that "[s]ome have suggested that the Office is determining obviousness in a way that stifles innovation by refusing patents for truly inventive subject matter." David Kappos, Director, U.S. Patent and Trademark Office, The Impact of KSR (Nov. 24, 2009), www.uspto.gov/blog/.

Rather than dispute that critique, however, the PTO has pledged merely to "review[] court decisions with an eye toward identifying factual scenarios to illustrate the developing law of obviousness." *Id.* Yet, devoting *more* attention to the Federal Circuit's errant jurisprudence will not correct the problem. Only this Court's review and reaffirmation of its prior decisions can undo the harm.

2. The practical implications of the question presented cannot be overstated. The Federal Circuit's rejection of a patent as "obvious" because it resulted from trying "viable option[s]" threatens to dampen innovation across a variety of industries that depend on research and development. Methodical experimentation with known building blocks is fundamental to scientific advancement. Indeed, "[m]any if not most pharmaceutical inventions are discovered through a routine screening protocol or through an established trial and error process." *Pfizer*, 488 F.3d at 1384 (Rader, J., dissenting from denial of rehearing en banc).

That research and development process depends upon enormous investments of resources, which will only be made if the potential for patent protection to recoup the investment exists. See, *e.g.*, Kristen C. Buteau, *Deuterated Drugs: Unexpectedly Nonobvious?*, 10 J. High Tech. L. 22, 22 (2009) (noting that "[t]he pharmaceutical industry depends heavily on the market exclusivity afforded by patent protection to recoup research and development costs associated with FDA-approval of new drugs"). On average, developing and securing regulatory approval for a new drug or biologic costs between $800 million and $1.2 billion. See Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* 2 (Oct. 2006) ("CBO Report"), *available at*

http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf.; PhRMA, *Pharmaceutical Industry Profile 2009*, at 38-39 (2009) ("Industry Profile"), *available at* http://www.phrma.org/files/attachments/PhRMA%202009%20Profile%20FINAL.pdf.

In addition, the path from research and development to regulatory approval takes an average of 12 years to complete. CBO Report at 2; see also Industry Profile at 36. During that time, the firm earns no return on its investment. And, the firm may never earn any return since "[o]nly one" of "every 10,000 compounds investigated" by America's research-based pharmaceutical companies "is ever approved for patient use." PhRMA, *What Goes Into the Cost of Prescription Drugs?* 2 (June 2005), *available at* http://www.phrma.org/files/attachments/Cost_of_Perscription_Drugs.pdf. Even with approval, "just two in 10 medicines ever produce revenues that match or exceed average R&D costs." Industry Profile at 39.

Given those dynamics, and that *most* attempts to develop a drug fail, the potential reward of patent protection is an essential incentive. The panel majority's decision threatens to shrink that incentive. As soon as the prior art has identified a finite number of particular, *viable* solutions to a problem, the patent incentives to continue investigating disappear, because any subsequent invention would be deemed "obvious to try." As Judge Baldwin cogently stated in dissent from a similarly erroneous obvious-to-try decision,

> The obvious-to-try analysis is an attack on the method of making an invention that specifically penalizes people in areas of endeavor where advances are won only by great effort and expense. The pharmaceutical field is particular-

> ly hard hit because there is an overabundance of structures that are obvious to try. . . . Under an obvious-to-try analysis, any of these structures which ultimately is shown to be effective . . . would be unpatentable because the researcher dared to follow a logical plan.

In re Merck & Co., 800 F.2d 1091, 1100 (Fed. Cir. 1986) (Baldwin, J., dissenting). In order to preserve the proper incentives for the design and development of critical pharmaceuticals, as well as innovations in other research-dependent industries, the Court should grant certiorari.

3. Although the Federal Circuit's erroneous standard is not new, its implications are especially problematic after *KSR*. Before *KSR*, the Federal Circuit applied a two-part test to determine whether a patent that combined principles of prior art was obvious. *E.g.*, *Medichem, S.A.* v. *Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). The first part asked whether the prior art provided a particular teaching, suggestion, or motivation to combine the prior art teachings. *Id.*; see also *KSR*, 550 U.S. at 413-14 (describing Federal Circuit's "TSM" test). Only if such a teaching, suggestion, or motivation were found, would the Federal Circuit then ask whether the combination justified a "reasonable expectation of success." *Medichem*, 437 F.3d at 1165.

Before *KSR*, the problems inherent in the second prong arose less frequently than they do today. That is because the court would not reach the second prong unless the court first found an explicit prior art teaching, suggestion, or motivation to try the claimed invention. Now, however, shorn of the overly exacting teaching-suggestion-motivation test, which *KSR* rejected, 550 U.S. at 419, the Federal Circuit is applying the improperly low second prong in iso-

lation. The resulting test eviscerates the proper standard of "predictability." This Court should finish the work it began in *KSR*, clarify that "obvious" in fact means "obvious," and reinvigorate the proper standard of patentability under § 103(a).

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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